

INTERNATIONAL ATOMIC ENERGY AGENCY SAFRAD

INSTRUCTIONS FOR THE LOCAL COORDINATOR

Introduction

While new equipment and techniques in radiology and cardiology are bringing new benefits, some of the radiological procedures involve the delivery of relatively high ionizing radiation doses to patients. In addition, a significant number of patients may be subject to repeated procedures and a number of radiation injuries ranging from transient erythema to skin necrosis in interventional radiology have been reported. These facts have focused attention on the need to improve the radiological protection of patients in diagnostic and interventional radiology. All patients for whom one (or more) of dose markers is exceeded should be subject to reporting, in order to follow them up to detect any effect that could be linked to the irradiation, and to feed a international database which is intended to be educational rather than repressive. The reporting system is voluntary and anonymous; this is meant to encourage participants in sharing their experience and information with others in the radiological community.

Many specialists outside radiology are involved in the use of radiation for diagnostic or therapeutic purposes like cardiologists, urologists, neurosurgeons, gastroenterologists, anaesthetists, orthopaedic surgeons, etc, but most of the SAFRAD procedures will probably be performed by either cardiologists or interventional radiologists.

The SAFety in RADiological procedures reporting system (SAFRAD) will focus on the reporting of exposures above the level for deterministic effects.

To broaden the scope of the SAFRAD reporting system to any unintended exposure, patient who receive the wrong procedure or wrong patients undergoing a procedure or pregnant women with no knowledge of the pregnancy at the time of procedure must also be reported.

Procedures using radiation can have both deterministic and stochastic effects. It is not known whether stochastic effects like cancer induction or genetic defects happen or not at low dose, so the assumption is that any dose can cause a stochastic effect, its probability growing with the dose. These effects cannot be reported due to the latency period that can be many years and the lack of proof for causality. On the other hand, deterministic effects are known to happen only above a threshold of at least 2 Gy.

The severity of deterministic effects is proportional to the dose and the organ at risk; which for the fluoroscopy procedures is the skin.

Table 1 : Deterministic effects, levels of exposure, time before onset

Effect	Threshold dose (Gy)	approximate delay to onset	equivalent fluoroscopy time (min)
Early transient erythema	2	2–24 hours	20
Main erythema reaction	6	1.5 weeks	60
Temporary epilation	3	3 weeks	30
Permanent epilation	7	3 weeks	70
Dry desquamation	14	4 weeks	140
Moist desquamation	18	4 weeks	180
Secondary ulceration	24	76 weeks	240
Late erythema	15	8–10 weeks	130
Ischaemic dermalnecrosis	18	10 weeks	180

Assignment of a coordinator

Each facility decides on a coordinator who will take responsibility for ensuring that :

- all relevant personnel are informed of the project and to distribute the relevant documentation
- the patient data is collected, stored securely, verified and submitted
- the relevant personnel know that they must inform the patient as to the procedure to be followed if they notice any change in skin colour at the site and are given details of the contact person
- patients who do not report when asked to do so are contacted by telephone by the relevant personnel at thirty days post procedure to confirm that there is no adverse reaction

The coordinator may designate other responsible persons

The coordinator will also be the contact point for possible questions from data management centre at the IAEA

Reportable events :

There are 5 trigger levels and 5 trigger events:

- Fluoroscopy time is greater than 60 minutes
- Kerma-Area Product (or Dose-Area Product) greater than 300 Gy.cm² for cardiac and neurological procedures, greater than 500 Gy.cm² for other procedures
- Cumulative air kerma at interventional reference point is greater than 5 Gy
- Measured Peak Skin Dose is greater than 3 Gy
- Number of cine acquisition series is greater than 20
- A radiation injury is observed
- The patient has had multiple procedures within the last 12 months
- The wrong procedure has been performed
- The procedure has been performed on the wrong patient
- The patient was pregnant and did not know it at the time of the procedure

The trigger values have been chosen so that not too many patients have to be recalled. Depending on the effects discovered upon the effective follow up of patients having exceeded these trigger levels, we may have to adjust the trigger levels.

If any of the trigger values are reached, then the case is to be reported and the patient is to be followed up in order to detect any sign of deterministic effect. If any of the trigger events happens, the event is to be reported in order to define an international database of such events.

The only way to identify those patients who are to be reported is to monitor ALL patients. All the available dose indicators should be reported.

In addition, any other data about the procedure that can be filled in will be helpful in assessing the reasons for a higher dose in a particular patient.

In order to be able to analyse the reasons for an exposure exceeding the trigger levels and consequently possibly exceeding a dose of 3 Gy at the skin level, a series of parameters have to be known. This will possibly allow correlations to be made between some of these parameters and doses to the skin approaching or exceeding the threshold for deterministic effects.

These parameters are patient-related, machine-related, procedure-related and operator-related. They all have to be registered **for all patients** if practically feasible so as to be available for reporting if any of the trigger levels is exceeded.

- Patient-related parameters
 - ID : for your own records, not to be submitted to SAFRAD
 - Age
 - Sex
 - Body weight
 - (height) : optional, needed to compute BMI
 - Radiation sensitivity-enhancing condition (diabetes, connective tissue illness, lupus...)
 - Name, dates and dosimetric indicators of anterior procedures (important since multiple procedures can be the cause of deterministic effect)
- Operator-related parameters
 - Specialist /junior (trainee, fellow)
- Procedure-related parameters
 - Time from start to finish
 - Complexity : simple/normal/difficult
- Equipment-related parameters
 - Use of fluoro /cine-acquisition /DSA
 - Continuous fluoro/pulsed fluoro (30 pps /15 pps /10pps /7.5 pps /3 pps etc..)
 - Doserate setting : high/normal/low
 - kV range (or average kV) during procedure
 - filtration (if displayed)
 - presence of anti-scatter grid
 - collimation
 - use of filters
 - field of view/magnification

- SSD (source to skin distance)
- SRD (source to image receptor distance)

To help register these data, Form 3 is provided. As many fields as possible in this form must be filled, depending on the availability of data and time and resources allocated to the project.

How to enter a reportable event?

The first step is to register the hospital using SAFRAD website.

The second step is to give additional information about the facility/department using SAFRAD website (add facility) and register all rooms, cathlabs, or mobile C-arms where cardiac or radiology interventional procedures will take place (add equipment). You will be required to assign an ID or code to any registered equipment. Also register the information about your annual workload. That will tell us the number of procedures that are performed at your institution each year, and will allow us to derive statistics on the incidence of high doses or unintended exposures.

This second step will allow all patient- or procedure-independent data to be stored in the reporting system, so that you only have to record and submit these data once. It is evident that this form has to be submitted again every time a new room is installed or every time a room is significantly upgraded.

You are now ready to monitor all interventional procedures taking place in the rooms you registered. One way of doing that is to use the downloadable patient data collection form and follow the instructions:

Prior to the procedure, reset the fluoro timer and verify that DAP/KAP meter is set to zero, note the time the examination starts.

Indicate facility ID and equipment ID.

Record patient details

- Name, ID number (for your records)
- Gender
- Age
- Weight
- Height
- BMI = weight (kg)/height² (m²)
- Presence of radiosensitivity-enhancing conditions (diabetes, connective tissue illness...)

During and after the procedure, register the procedure details

- Procedure name
- Physician
- Date
- Start and end time
- Presence of anti-scatter grid
- SSD (source-skin distance)
- SID (source-image receptor distance)

- FOV (fields of view)
- Modality : DSA, cine, fluoroscopy
 - Dose mode (low/normal/high/low noise/high quality...)
 - Pulse rate (if pulsed fluoroscopy used)
 - Image rate for cine runs
 - Range of kV
 - Filtration (if displayed or known)
 - mA/kV curve used (if more than one available)
 - type and use of collimation (manual/electronic)
 - type and use of filters

After the procedure, note time of end of procedure and record dose indicators

- total KAP (or DAP) in Gy.cm² (or cGy.cm² or μGym²) making sure it includes all cine and fluoroscopy exposure
- K_{a,r}, cumulative Air-Kerma at interventional reference point in mGy
- fluoroscopy time in min
- number of cine images
- number of cine series or runs

Also record if an unintended procedure was performed or if multiple procedures have been recently performed on the patient.

You can enter you patient data using SAFRAD website (add patient).

If any of the trigger levels is exceeded, enter the patient procedure data as an EVENT REPORTING FORM (add report)

If a trigger event has happened, also send a report.

The follow up of patients.

Patients that are entered in SAFRAD should be told that they are going to be followed up, and be made aware of the extremely slight risk of deterministic effect. They must be provided with contact details of the person responsible for follow-up of patients. The coordinator must ensure that the person responsible for follow-up knows what to expect in terms of radiation injury and fills in SAFRAD downloadable follow-up form.

Patients must contact the facility between 1 and 37 days after the procedure to report on their skin condition. The follow-up can be done by telephone if the patient is able to see the area that was submitted to X-ray or if a relative or carer can answer the questions.

The questions are :

- Is the skin of your back reddened?
- Is the appearance of the skin of your back changed?
- Have you experienced any unusual itching?

If the answer is yes to any of these questions, the patient should be seen by a doctor. The doctor may be the interventionalist, the dermatologist or the general practitioner. All of them must be provided with guidelines to help them recognize radiation injuries.

Any complaint at any time by the patient should be recorded.

The patient follow-up form should be filled after a contact has been made by the patient before the 30th day after the procedure. If the patient did not contact the facility, then staff will contact the patient at day 37 after the procedure.

The reporting of events

The patient data collection form should be kept together with the patient follow-up form until the 37th day post-procedure. When patient follow-up form is filled, it can be uploaded for reporting with event reporting approximately 60 days post-procedure.

Any adverse effect occurring after day 37 post-procedure will be sent to SAFRAD as a separate event, and entered manually in the reporting system. It is expected that there will be very few of these late effects.

References

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